REMARKS

Claims 1, 6-12, and 35-41 were pending in the application. Claim 1 has been amended and claims 35-41 have been canceled. Accordingly, upon entry of the instant response, claims 1 and 6-12 will be pending.

Claim 1 has been amended to specify that monomeric IgA and the agent are linked by chemical conjugation or recombinant genetic fusion. Support for this amendment can be found throughout the specification and the claims as originally filed. Specifically, support is present, at least, for example, at page 13, lines 1-7 of specification. Additional support is present in U.S. Patent 5,922,845 at column 2, lines 26-29 and column 15, lines 8-27; and U.S. Patent 6,018,031 at column 14, lines 57-62 (both of which are explicitly incorporated by reference into the present specification at page 13, lines 4-7).

No new matter has been added. The foregoing claim amendments should in no way be construed as an acquiescence to any of the Examiner's rejections and were made solely in the interest of expediting prosecution of the application. Applicant reserves the right to pursue claims covering any subject matter canceled herein in this or a separate application(s).

Rejection of Claims 1 and 6-12 Under 35 U.S.C. § 112, First Paragraph – New Matter

The Examiner has maintained the rejection of claims 1 and 6-12 under 35 U.S.C. § 112, first paragraph, as introducing new matter. Specifically, the Examiner asserts that the specification lacks support for methods of treating cancer and infections (*e.g.*, bacterial, viral and fungal infections) using monomeric IgA and an antibody (or fragment thereof) which specifically binds to the target cell (*e.g.*, cancer cell or bacterial, viral or fungal antigen).

Applicant respectfully traverses this rejection for the reasons previously made of record. Specifically, it is clear from the specification that the invention is based on the discovery that monomeric (serum) IgA binds to FcαR-expressing cells and causes elimination (*e.g.*, phagocytosis) of antigens or target cells bound to monomeric IgA (see, for example, the first paragraph of the Summary of the Invention at page 2, lines 20-26). Accordingly, the very focus of the present application is to harness this feature of monomeric IgA to eliminate a target cell (*e.g.*, a cancer cell) or antigen (*e.g.*, bacteria, virus or fungus) from the circulatory system of a subject, as currently claimed. Specifically, support for the presently claimed methods is

available at least, for example, at page page 2, line 20 through page 3, line 32; page 12 (lines 33-35); page 13 (lines 1-21); page 14 (lines 19-33); and in original claims 1-3 and 7-8. Indeed, it is clear that the use of monomeric IgA for treating cancer and infections (*e.g.*, bacterial, viral and fungal infections) is not only explicitly contemplated within the four corners of the present specification, but also is the central aspect of the invention.

In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdrawn this rejection.

Rejection of Claims 1 and 6-12 Under 35 U.S.C. § 112, First Paragraph – Enablement

Claims 1 and 6-12 are rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner states that the specification does not reasonably provide enablement for a method of eliminating a target cell or antigen from the circulatory system of a subject comprising administering monomeric IgA and an agent/antibody/antibody fragment that binds a target cell or antigen as embraced by the claims.

Applicant respectfully traverses this rejection for the reasons previously made of record. Contrary to the Examiner's assertion, Applicant does, indeed, enable the claimed methods. For example, Applicant provides a detailed description of the composition employed by the presently claimed methods, which would enable one enable one of ordinary skill in the art to perform these methods. Specifically, Applicant teaches that the composition used in the presently claimed methods has a first binding specificity, which binds FcαRI, linked to a second binding specificity, which binds to a target cell or antigen. Applicant further teaches that first binding specificity can be monomeric IgA, as presently claimed (page 3 (lines 1-2), page 14 (lines 22-35) and original claims 1-3). Applicant teaches that the second binding specificity can be an antibody (or fragment thereof) or a ligand which binds to a receptor on the target cell (page 12 (lines 33-37). Applicants further describe techniques (*e.g.*, chemical conjugation or genetic (recombinant) fusion) for linking the two portions of the composition (see page 2 (lines 35-37) and page 13 (lines 1-7).

Thus, based on the teachings in the specification, as well as knowledge available in the art, the ordinarily skilled artisan would be able to make and use the claimed invention using only

routine experimentation. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdrawn this rejection.

Rejection of Claims 35-36 Under 35 U.S.C. § 112, First Paragraph – Written Description

Claims 35-36 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not meeting the written description requirement. Specifically, the Examiner is of the opinion that specification would not have led one of ordinary skill in the art "to the claimed method of administering monomeric IgA for the elimination of cancerous cells." The Examiner further asserts that the disclosure on page 9, line 7 of the specification that "[t]umor specific mAb of human IgA class are not available" would not have led one skilled in the art to the presently claimed methods of eliminating a cancer cell from a subject by administering monomeric IgA.

Applicant respectfully traverses this rejection. However, to expedite prosecution, claims 35-36 have been canceled, thereby rendering this rejection moot. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection

Rejection of Claims 35, 37 and 40-41Under 35 U.S.C. § 102(b) - Novelty

Claims 35, 37 and 40-41 are rejected as being anticipated by Mannhalter *et al.* (U.S. Patent No. 5,808,000). The Examiner relies on Mannhalter *et al.* for teaching a method of treating inflammations, infections and allergies, including bacterial and viral infections in a subject comprising administering monomeric IgA by intravenous injection.

Claims 35, 37 and 40-41 have been canceled to expedite prosecution, thereby rendering this rejection moot. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

Rejection of Claims 35 and 37-41 Under 35 U.S.C. § 103 - Obviousness

Claims 35 and 37-41 are rejected as being obvious over Mannhalter *et al.* (U.S. Patent No. 5,808,000) in view of Deo *et al.* (*J Immunol.* 1998 Feb 15;160(4):1677-86). The Examiner relies on Mannhalter *et al.* for the reasons set forth above. While the Examiner acknowledges that Mannhalter *et al.* "do not specifically teach administration of a cytokine selected from GM-CSF, IL-6, IL-1β, IL-8 and TNF-α," the Examiner asserts that Deo *et al.* cures this deficiency. The Examiner relies on Deo *et al.* as teaching that "only FcαRI expression can be enhanced by TNF- α or GM-CSF and IgA immune complexes or monoclonal antibodies specific for epitopes

within or outside the FcαRI ligand binding domain stimulates degranulation, superoxide release, secretion of inflammatory cytokines, endocytosis and phagocytosis." The Examiner concludes that it would have been obvious to "have produced a method of treating inflammations, infections and allergies, including bacterial and viral infections in a subject comprising administering monomeric IgA and GM-CSF or TNF-α."

Claims 35 and 37-41 have been canceled to expedite prosecution, thereby rendering this rejection moot. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

CONCLUSION

In view of the foregoing amendments and arguments, reconsideration and withdrawal of all the rejections and allowance of this application with all pending claims are respectfully requested. If a telephone conversation with Applicant's Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call (617) 227-7400.

Applicant believes no additional fee is due with this response. However, if an additional fee is due, please charge our Deposit Account No. 12-0080, under Order No. CXI-170RCE3 from which the undersigned is authorized to draw.

Dated: November 4, 2008

Respectfully submitted,

By _____

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